

### **Remarks**

After entry of the foregoing amendments, claims 1, 3, 4, 7-10, 12-22 and 37-40 are pending. Claims 1, 7-10, 12-14, 16, 21, and 22 have been amended, and claims 38-40 are newly added. Claims 5, 6, and 11 are cancelled. Support for the amendments to claims 1 and 16 may be found at least at original claims 7-10 and at page 4, lines 19-20 (hair follicle cells); support for the amendments to claim 21 may be found at least in original claim 16. Support for claims 38-40 may be found at least in original claims 7-10, at page 7, line 29 of the specification (cultured cells). Claims 7-10 and 12-14 were amended so that they depend on a non-cancelled claim. Claim 22 was amended to correct its dependency. Support for the amendment to the specification may be found at least in original claim 10.

Applicant thanks the Examiner for the indication that claims 7-10 and 37 contain allowable subject matter.

#### ***Rejection Under § 112***

Claim 22 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, because there is no antecedent basis for the limitation “polymer solvent.” Applicant has amended claim 22 to correct the dependency. The amendment renders the rejection moot and Applicant respectfully request that the rejection be withdrawn.

#### ***Rejections Under § 102***

*U.S. Patent No. 5,545,208*

Claims 1, 4, 5, and 11-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,545,208 (“the ‘208 patent”). The Office action cites the ‘208 patent as disclosing a prosthesis for controlled delivery of drugs at the site of implantation. The Office action asserts that the disclosed prosthesis comprises a filamentary metal core and a drug carrying bioabsorbable porous polymer coating that overlays at least a portion of the metal.

The Office action asserts that the '208 patent discloses poly-l-lactic acid/polyglycolic acid and polyanhydride as the bioabsorbable polymers.

The Manual of Patent Examining Procedure ("MPEP") §2131 states that, in order to anticipate a claim, a reference must teach every element of the claim:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1222, 1236 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989).

Applicant respectfully submits that the amendments to claim 1 obviate the rejection over the '208 patent. The '208 patent does not teach the claimed filamentary structure...comprising a filament comprising a solid core and a porous sheath, and an agent selected from the group consisting of hair follicle cells, genetically engineered cells, encapsulated cells, and cell signaling molecules. (Language of claim 1 underlined.)

The cancellation of claims 5 and 11 obviates the rejection of those claims over the '208 patent. Further, claims 4 and 12-14, which depend from claim 1, and therefore incorporate the limitations of claim 1, are patentable for at least the same reasons as claim 1. Thus, Applicant respectfully requests that the rejection of claims 1, 4, 5, and 11-14 over the '208 patent be withdrawn.

*U.S. Patent No. 5,486,593*

Claims 16, 17, 20, and 22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,486,593 ("the '593 patent"). The Office action cites the '593 patent as disclosing bioabsorbable and/or biodegradable solid fibers coated with a polymer to form a core-sheath structure. The Office action asserts that '593 patent discloses coating drugs, such as growth factor, on the porous layer.

Applicant respectfully submits that the '593 patent does not anticipate claims 16, 17, 20, and 22. As indicated in past responses, which are incorporated herein by reference, the '593 patent does not teach a metal filament coated with a porous polymer and it does not teach a method of making such a filament. Thus, Applicant submits that the rejection of claims 16, 17, 20, and 22 as anticipated by the '593 patent is improper as the '593 patent does not teach each and every element of the claimed invention, either expressly or inherently. Applicant, therefore, requests that the rejection of claims 16, 17, 20, and 22 as anticipated by the '593 patent be withdrawn.

Moreover, Applicant respectfully submits that, contrary to the Office action's assertion, the polymer solvent of the '593 patent is not inherently a pore forming agent. The '593 patent does not teach that the polymer solvent can be a pore forming agent. Instead, it teaches that an additional agent, such as a filler, binder, additive or gaseous or chemical foaming agent, is necessary for pore formation. The '593 patent specification states:

The fibers of this invention may also be porous. These fibers can be formed by the addition of fillers, binders, additives and components which were added to the biopolymer before or during fiber formation which are removed or leached from such fibers at some stage to form a porous or semi-porous system. In addition, gas foaming during the extrusion of the fibers either by gaseous foaming agents e.g., N<sub>2</sub>, He, Ar, NE, Air, and the like, or chemical foaming agents can be utilized to achieve a porous or somewhat porous structure.

('593 patent at col. 7, lines 17-26, emphasis added.) Thus, Applicant respectfully submits that the '593 patent does not anticipate claim 22 because the '593 patent fails to teach that the polymer solvent may be the pore forming agent.

### ***Rejections Under § 103***

*U.S. Patent No. 5,545,208*

Claims 3 and 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '208 patent in view of U.S. Patent Application No. 2004/0039438 ("the '438 application"). The Office action cites the '438 application as disclosing the metals of claim 3, including nickel, stainless steel, chromium, titanium, or alloys thereof.

Applicant respectfully asserts that the Office action has failed to establish a *prima facie* case of obviousness for claim 3. MPEP §2141.03 states:

"To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970).

As discussed above, the '208 patent does not teach or suggest a filamentary structure...comprising a filament comprising a solid core and a porous sheath, and an agent selected from the group consisting of hair follicle cells, genetically engineered cells, encapsulated cells, and cell signaling molecules. (Language of claim 1 underlined.) The '438 application is also directed solely to stents for deployment in a blood vessel of a human body, and therefore, does not cure the deficiencies of the '208 patent. Moreover, Applicant submits that the '438 application is not analogous art, and therefore, is not a proper reference against the present application. Therefore, Applicant respectfully requests that the rejection of claim 3 be withdrawn.

Although the Office action acknowledged that the '208 patent does not teach the pore size limitation in claim 15, the Office action asserted that the pore size does not impart patentability to the claims, absent evidence to the contrary. Applicant respectfully submits that the Office action has failed to set forth a *prima facie* case of obviousness for claim 15, as the combined references fail to disclose all the limitations of the claimed invention. The

Office action has failed to cite any reference that teaches the claimed filamentary structure wherein the open pores are large enough to admit molecules ranging in molecular weight from about 500 to about 100,000 Daltons. (Language of claim 15 underlined.) Moreover, claim 15 indirectly depends on claim 1, and therefore is patentable over the cited references for at least the reasons expressed above with respect to claims 1 and 3. As the Office action has failed to set forth a *prima facie* case of obviousness for claim 15, Applicant respectfully requests that the rejection of claim 15 be withdrawn.

Claim 6 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the '208 patent in view of U.S. Patent Application No. 2002/0049426 ("the '426 application"). The Office action acknowledges that the '208 patent does not teach that cells may be delivered using the disclosed prosthesis. The '426 application is cited to cure the deficiencies of the '208 patent. The Office action cites the '426 application as teaching a cylinder apparatus to be implanted in the body to deliver active agents including cells embedded in a polymeric material. Applicant respectfully submits that the cancellation of claim 6 has obviated this rejection and requests that it be withdrawn.

*U.S. Patent No. 5,486,593*

Claims 18, 19, and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '593 patent in view of U.S. Patent No. 4,104,195 ("the '195 patent"). The Office action asserts that the '593 patent discloses a process for making a core-sheath structure comprising a bioabsorbable and/or biodegradable solid fiber coated with a polymer through melt extrusion followed by solution dipping with the pores formed using chemical foaming agents. The Office action also asserts that the fibers of the '593 patent may contain drugs, such as growth factor, coated on the porous layer. In addition, the Office action asserts that the fibers of the '593 patent can comprise titanium, metal alloys such as chromium, cobalt,

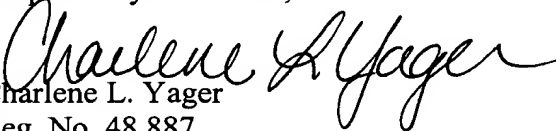
and molybdenum. The Office action acknowledges that the '593 patent does not teach the foaming agents of claims 18 and 19 and cites the '195 patent to cure this deficiency.

As is stated above, Applicant respectfully submits that the '593 patent does not teach or suggest a method for making a filamentary structure wherein the solid core is a metal or an alloy. The '593 patent discloses bioabsorbable polymers on objects (e.g. Col. 5, lines 49-51) made of metals (e.g. Col. 19, lines 40-42), yet none of these metal objects were metal wire, needles, or filaments. In fact, the '593 patent's bioabsorbable polymer coatings were used only on woven or knitted fibers, and were used only for the purpose of sealing non-bioabsorbable vascular grafts against fluid leaks during surgery. Such vascular grafts are constructed from synthetic polymer fibers and not from metal filaments. The present invention, by contrast, uses single metal filaments in combination with bioabsorbable polymers, to deliver the coating and its cells or other agents into the living tissue of the recipient. The '195 patent does not cure this deficiency. Thus, Applicant respectfully requests that the rejection of claims 18, 19, and 21 be withdrawn.

### **Conclusion**

Applicant respectfully submits that all claims, as amended, are in condition for allowance. Should any issues remain, the Examiner is invited to contact the undersigned at the phone number below.

Respectfully submitted,

  
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